



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/562,955

08/03/2006

Robert T. Tranquillo

890003-2008.1

4010

27805

7590

12/23/2008

THOMPSON HINE L.L.P.  
Intellectual Property Group  
P.O. BOX 8801  
DAYTON, OH 45401-8801

EXAMINER

FORD, ALLISON M

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Interview Summary</b>	<b>Application No.</b> 10/562,955	<b>Applicant(s)</b> TRANQUILLO ET AL.	
	<b>Examiner</b> ALLISON M. FORD	<b>Art Unit</b> 1651	

All participants (applicant, applicant's representative, PTO personnel):

(1) Allison Ford. (3) \_\_\_\_.

(2) Gwen Wood (Applicant's representative). (4) \_\_\_\_.

Date of Interview: 18 December 2008.

Type: a) ☒ Telephonic    b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant    2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes    e) ☒ No.  
If Yes, brief description: \_\_\_\_.

Claim(s) discussed: all, particularly 2, 27, 28, 53-55 and 57.

Identification of prior art discussed: all, particularly Niklason et al (Science 1999).

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Allison M. Ford/ Examiner, Art Unit 1651	
--	--

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

#### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Applicant's representative presented proposed amendments to the claims and arguments against the rejections of record.

With regards to the method claims of claims 2 and 55, differences between the claimed method and the method of Niklason et al were discussed, particularly how the smooth muscle cells and endothelial cells are initially provided to the matrix. The instant invention intends to supply the SMCs and ECs to the matrix in a manner such that the cells are not provided in two adjacent cell layers (such as in Niklason et al), but rather in a manner such that the cells from both populations are intermixed within one another, and the ECs only migrate out to form a distinct layer upon application of the attractant factors. Applicants were encouraged to better define the method by which the SMCs and ECs are provided to the matrix, so as to differentiate from the method of Niklason et al.

The product claims of claims 28 and 55 are drawn to the matrix, comprising the SMCs and ECs as initially seeded (i.e. before migration of the ECs to form a separate layer, due to attractant factors); again better defining the relationship of the SMCs and ECs to differentiate from that of Niklason et al would be remedial.

With regards to the product claims of claims 27, 53 and 54, it was discussed that product claims, even product-by-process claims, are considered for their structure. Unless the method of making the product imparts a distinct structure to the product a prior art product with the same structure will anticipate the claimed product even if made by a different process. Applicants were encouraged to point out structural distinctions between the tissue engineered blood vessels of claims 27, 53 and 54, and the tissue engineered blood vessel of Niklason et al.

Furthermore it was discussed how Applicants may better clarify what factors (or combinations thereof) are required in the claimed methods, as the recitation of what factors are required is still not clear. Applicants were encouraged to re-write the claim language so as to show the possible combinations as different species, for example:

" a) adding one or more factors, wherein the factors are:

- (i) one or more attractant factors and one or more mitogenic factors;
- (ii) one or more mitoattractant factors and one or more mitogenic factors; or
- (iii) one or more attractant factors, one or more mitoattractant factors and one or more mitogenic factors"

This suggested language is not required, but is merely intended to clarify that the precise components required need to be clearly set forth.

Finally, the rejection under 35 USC 103(a) over Niklason et al, in view of Henrickson, and further in view of Tu was discussed: specifically it was clarified that Tu was only relied upon to show that inclusion of VEGF would have been obvious. Claims 1-6, 13, 14, 16, 28-32, 39 and 40 were included in the rejection because they were anticipated by Niklason et al. Showing the invention is not anticipated by Niklason et al would obviate the rejection over Niklason et al in view of Tu et al.